IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

GENE SCHURMAN, Plaintiff, vs. JANSSEN PHARMACEUTICALS, INC., ET AL., Defendants.	Case No. 3:15-cv-01180-SMY-DGW

PLAINTIFF'S OPPOSITION TO DEFENDANT MITSUBISHI TANABE PHARMA'S MOTION TO DISMISS COMPLAINT UNDER F.R.C.P. 12(B)(2) AND 12(B)(6)

In its motion to dismiss, Mitsubishi asserts it had no involvement in Plaintiff's alleged injuries, that this Court has no personal jurisdiction over it, and even if personal jurisdiction does exist, any claims Plaintiff asserts are preempted. In making these arguments, Mitsubishi ignores important allegations in the Complaint. Specifically, Mitsubishi collaborated and partnered with the Johnson & Johnson Defendants and participated in the research, development, design, licensing, manufacture, distribution, supply, sale, marketing, and introduction into interstate commerce of Invokana®, which was ingested by and caused injury to Plaintiff. *Compl.* at ¶¶ 10, 18–19, 33, 37. Mitsubishi entered into a licensing agreement whereby its co-Defendants acquired the rights to market and distribute Invokana in the United States. *Id.* at ¶¶ 18–19. Moreover, Mitsubishi actively participated in the FDA approval process for Invokana. *Id.* at ¶ 69. In fact, the research and development *conducted by Mitsubishi* was submitted to the FDA in support of Invokana's NDA. *See FDA Med. Review of Invokana* at 29–30, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000MedR.pdf (Feb. 8, 2013).

With respect to its preemption claims, Mitsubishi raises factual issues outside of the Complaint — disputed questions of fact that are premature and inappropriate for a motion to

dismiss. For example, Mitsubishi would have the Court believe it had no involvement with Invokana's development or approval, asserting that its co-Defendant submitted the NDA, and therefore Mitsubishi had no ability to influence the approval and labeling of the drug. However, the FDA refers to Mitsubishi as the "sponsor's partner," *id.* at 29, and Plaintiff's Complaint alleges that Mitsubishi did in fact participate in the drug approval process, including the labeling. *Compl.* at ¶ 69. Only after discovery will the extent of Mitsubishi's involvement be known. At this stage in the litigation, Plaintiff's Complaint alleged sufficient facts for a "plausible" claim for relief against Mitsubishi. Therefore the Motion to Dismiss should be denied.

ARGUMENT

A. This Court Has Personal Jurisdiction Over Mitsubishi.

Mitsubishi's conduct in acting with its collaboration partners to research, develop, design, and obtain FDA approval of Invokana for sale in Illinois, and the ultimate distribution and sale in Illinois, of the Invokana that injured Plaintiff in Illinois, subjects Mitsubishi to jurisdiction in Illinois. Specific jurisdiction arises out of or relates to a defendant's contacts with the forum. *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414, n.8 (1984).[1] The inquiry "focuses on the relationship among the defendant, the forum, and the litigation." *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). As this Court is sitting in diversity, jurisdiction is defined by the Illinois long-arm statute, which "permits the exercise of jurisdiction to the full extent permitted by the Due Process Clause." *Tamburo v. Dworkin*, 601 F.3d 693, 700 (7th Cir. 2010). The exercise of jurisdiction comports with due process if a defendant has "minimum contacts" with the forum "such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945).

A state has a "manifest interest" in providing its residents with a convenient forum for

[1] Plaintiff claims that Mitsubishi is subject specific personal jurisdiction, not general personal jurisdiction.

"redressing injuries inflicted by out-of-state actors," particularly where the defendant "purposefully avails itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 473 & 475 (1985). In accordance with well-established precedent, deliberately placing products into the stream of commerce with the knowledge and intent that they will be sold in the forum constitutes purposeful availment. *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 298 (1980); *Dehmlow v. Austin Fireworks*, 963 F.2d 941, 946–48 (7th Cir. 1992).

Defendant disputes this jurisdictional rule, claiming the plurality opinion in *J. McIntyre Machinery, Ltd. v. Nicastro*, 131 S. Ct. 2780 (2011), altered the "stream of commerce" theory of jurisdiction. This argument, however, fails to recognize the effect of a plurality opinion. "When a fragmented Court decides a case and no single rationale explaining the result enjoys the assent of five Justices, the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds." *Marks v. United States*, 430 U.S. 188, 193 (1977) (internal quotations omitted). In *J. McIntyre*, the concurrence made no new law, explicitly adhering to established precedents. 131 S. Ct. at 2792 (Breyer, J., concurring). Circuit Courts interpreting the case therefore conclude that Justice Breyer's concurrence provides the holding of the Court. *See, e.g., Ainsworth v. Moffett Eng'g, Ltd.*, 716 F.3d 174, 178 (5th Cir. 2013).[2] As *J. McIntyre* made no change to the jurisdictional framework, courts continue to apply their existing stream-of-commerce precedent. *Id.* at 178–79. And under existing Seventh Circuit precedent, Mitsubishi is subject to jurisdiction. *See, e.g., Dehmlow*, 963 F.2d at 947.[3]

[2] The Seventh Circuit has not yet determined how *J. McIntyre* affects stream-of-commerce jurisprudence.

[3] Even if *J. McIntyre* could affect stream of commerce jurisprudence, any changes would not apply in these circumstances. *J. McIntyre* only applies, if at all, in circumstances in which a product was not "sold in sizeable quantities." *J. McIntyre*, 131 S. Ct. at 2795 (Ginsburg, J., dissenting). *See also id.* at 2793 (Breyer, J., concurring) (limiting concurrence to cases involving single isolated sales of a product). As set forth below, Invokana's sales in Illinois were quite sizeable, amounting to many millions of dollars in a single year.

Mitsubishi designed, developed, and supported the FDA approval of Invokana in collaboration with its co-Defendants, and then entered into a licensing and distribution agreement with them with the intent that Invokana be sold throughout the U.S., including in Illinois. *Compl.* at ¶¶ 10, 18–19. Defendants, whether directly or through their agents, collectively licensed, marketed, distributed, and sold Invokana in Illinois with the reasonable expectation that Invokana would be used in Illinois. *Id.* at ¶¶ 8–10, 12. Defendants, directly or through their agents, collectively conducted sales and marketing campaigns in Illinois to promote Invokana to Illinois residents, including Plaintiff. *Id.* at ¶¶ 12, 31. And they disseminated false and misleading information to health care professionals in Illinois with the expectation that such information be used and relied on in Illinois. *Id.* at ¶ 13. As a result of these acts, Plaintiff was prescribed Invokana in Illinois, ingested Invokana in Illinois, and suffered severe injury in Illinois. *Id.* at ¶¶ 7, 15, 32–35, 37, 45. Moreover, Mitsubishi transacted and solicited a significant amount of business in Illinois through its agents and representatives, deriving a substantial amount of revenue from Illinois. *Id.* at ¶¶ 12, 14. U.S. sales of Invokana were robust, totaling $278 million in just the first quarter of 2015, *id.* at ¶ 20, and exceeding ***$1.2 billion*** in 2015.[5] Illinois sales figures are not available without discovery. However, it is reasonable to infer that sales in Illinois amounted to at least 1/50th of the total sales generated by Invokana's nationwide marketing campaign, which is a very substantial sum.

Mitsubishi's agreement with Janssen shows it intended for Invokana to be marketed and purchased throughout the United States. Therefore, Mitsubishi must have intended Invokana to be marketed and purchased in Illinois, the fifth largest State in the nation. *Garrard v. Pirelli Tire LLC*, No. 11-824, 2012 U.S. Dist. LEXIS 85066, *6 (S.D. Ill. June 20, 2012) (Murphy, J.). Given

[5] *See Johnson & Johnson Reports 2015 Fourth-Quarter Results* at 9, *available at* http://files.shareholder.com/downloads/JNJ/1770895543x0x886536/96BAC352-6DF4-46A7-BA99-264160C2190E/JNJ_Q4_release.pdf.

the magnitude of Invokana's sales, Mitsubishi's contacts are more than sufficient to satisfy jurisdictional requirements. *uBID, Inc. v. GoDaddy Grp.,* 623 F.3d 421, 428–29 (7th Cir. 2010). Therefore, Mitsubishi is subject to personal jurisdiction in Illinois. *See, e.g., Id.* (internet retailer's significant revenue subjected it to jurisdiction in Illinois); *Dehmlow,* 963 F.2d at 947 (sales to distributor with expectation that products will be purchased in Illinois subjects party to jurisdiction); *Ainsworth*, 716 F.3d at 178–79 (Irish entity selling products in U.S. through distributorship agreement subject to jurisdiction); *O'Neal v. Bumbo Int'l Trust*, 16 F. Supp. 3d 952, 959 (S.D. Ind. Apr. 14, 2014) (South African entity selling products in U.S. through distribution network subject to jurisdiction); *Garrard*, 2012 U.S. Dist. LEXIS 85066, *6 (German company selling through distributor subject to personal jurisdiction in Illinois).

Mitsubishi's reliance on *Tile Unlimited, Inc. v. Blanke Corp.*, 47 F. Supp. 3d 750 (N.D. Ill. 2014), is misplaced. The case is distinguishable and Mitsubishi distorts its holding. *Tile Unlimited* expressly recognized that *J. McIntyre* "maintaine[ed] the status quo of the Court's stream of commerce jurisprudence." *Id.* at 756, n.6. Based on this status quo, the court found a foreign defendant whose products were sold infrequently in the forum state (only $16,400 in sales over a four year period) was not subject to personal jurisdiction. *Id.* at 759. By contrast, Invokana's U.S. sales exceeded $1.2 billion in a single year. Without discovery, Plaintiff cannot say what percentage of those sales came from Illinois, but it indisputably amounted to many millions of dollars. And as recognized by *Tile Unlimited*, when a party "earns many millions of dollars annually from Illinois customers … [i]ts contacts cannot fairly be described as random, fortuitous, or attenuated." *Id.* at 760 (quoting *uBid, Inc.*, 623 F.3d at 428–29).[6]

[6] Mitsubishi also cites *Noboa v. Barcelo Corporacion Empresarial, SA*, 812 F.3d 571, 572 (7th Cir. 2016), for the premise that contacts with the forum must be intentional to support personal jurisdiction. Unlike *Noboa*, Plaintiff's allegations show intentional conduct. In *Noboa*, an Illinois resident used a travel website to reserve a hotel in Mexico. While in Mexico, she booked an eco-tour operated by an unrelated entity and was injured while on the

The Complaint alleges that Mitsubishi developed Invokana with the intent that it be sold in Illinois, derived substantial revenue from the sale of Invokana in Illinois, and, with its co-Defendants, marketed and sold Invokana in Illinois. Accordingly, Mitsubishi has minimum contacts with the State of Illinois and is subject to personal jurisdiction in Illinois.[7]

B. Plaintiff's Claims Are Not Preempted.

Next, Mitsubishi tries to shoehorn this case, which involves a brand-name drug, into the Supreme Court's generic drug preemption decisions *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharmaceutical Company v. Bartlett*, 133 S. Ct. 2466 (2013), arguing that Plaintiff's claims are preempted as a matter of law under two distinct legal theories. First, Mitsubishi claims it is entitled to design, develop, and profit from a drug, yet avoid all liability for the damages caused, simply because it entered into a licensing agreement with Janssen. Second, Mitsubishi asks the Court to broaden the holding in *Bartlett*, and find brand name drug manufacturers cannot be held liable for damages caused by defects in their products *even if they know the drug they designed, marketed, and sold is unreasonably dangerous*. In essence, Mitsubishi seeks to reap the profits from its enterprise, immune from liability. Even if the Court wished to entertain these faulty legal theories, they implicate fact-specific issues that cannot be addressed prior to discovery. Therefore, Mitsubishi's preemption arguments are both premature and without merit.

1. Entering Into a Licensing Agreement Does Not Grant Immunity from Suit.

Mitsubishi "is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate

tour. The Court held that the chain-of-causation theory did not establish Illinois jurisdiction over the hotel or tour provider because the suit alleged no "accident-related contacts with Illinois." *Id.* at 572. Here, Mitsubishi's products were sold in Illinois, ingested in Illinois, and caused injury in Illinois, all of which constitute "accident-related contacts with Illinois."

[7] In the alternative, to the extent the Court finds Plaintiff's allegations insufficient, Plaintiff requests the opportunity to take discovery to further develop jurisdictional facts. *See* Section D, *infra.*

commerce, either directly or indirectly through third parties or related entities, … the prescription drug INVOKANA." *Compl.* at ¶ 10. After designing and developing Invokana, Mitsubishi entered into licensing agreement with Janssen, whereby its co-Defendant acquired the rights to market and distribute Invokana in the U.S. *Id.* at ¶¶ 18–19. Mitsubishi now claims that Janssen holds the NDA for Invokana. Based on this, Mitsubishi suggests it is like a generic drug manufacturer, unable to change the design or labeling of Invokana, and therefore immune from liability. Mitsubishi's entire preemption argument is based on the identity of Invokana's NDA holder, a factual issue outside of the Complaint. Pursuant to Rule 12(d), the Court should either exclude this extraneous material or convert Defendant's motion to one for summary judgment, first giving Plaintiff ample notice and time to conduct the necessary discovery. Fed. R. Civ. P. 12(d). However, should the Court take judicial notice of Mitsubishi's factual assertion, the Court must construe all facts "in the light most favorable to the [Plaintiff]." *Papasan v. Allain*, 478 U.S. 265, 283 (1986). The facts do not support preemption.

In inserting this factual issue, Mitsubishi conveniently neglects to mention that it actively participated in the FDA approval process. The FDA's medical review of Invokana identifies Mitsubishi as "the sponsor's partner," and explains that it received and relied on Mitsubishi's research and clinical trials during the approval process. *FDA Medical Review of Invokana* at 29–30, *available at* www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000MedR.pdf (Feb. 8, 2013).[8] As this motion was filed before Plaintiff received any discovery from Mitsubishi, Plaintiff lacks access to the necessary evidence to determine the full extent of Mitsubishi's involvement in the approval process or its influence over other pivotal issues

[8] A party opposing a Motion to Dismiss is subject to less stringent evidentiary limitations and "may submit materials outside the pleadings to illustrate the facts the party expects to be able to prove." *Geinosky v. City of Chicago*, 675 F.3d 743, 745, n.1 (7th Cir. 2012). These facts may be considered by the Court without triggering a Rule 56 conversion. *Id.*

affecting the design, labeling, marketing, and promotion of Invokana.[10] However, it is clear that Mitsubishi is not the powerless bystander it claims to be. Construing all facts in the light most favorable to Plaintiff, Mitsubishi certainly cannot show preemption should apply.

The case *In re Actos (Pioglitazone) Products Liability Litigation*, MDL No. 2299, 2014 U.S. Dist. LEXIS 121648 (W.D. La. Aug. 28, 2014), examined many of these same issues, albeit with the benefit of a fully developed record. In *Actos*, claims were filed against two drug companies, Takeda and Eli Lilly, for damages caused by a brand name drug. The defendants had a co-promotion agreement regarding the sale of Actos in the U.S., but Takeda held the NDA. *Id.* at *18, 49–51. The jury ultimately entered a verdict against both defendants. *Id.* at *63–64. Eli Lilly sought post-judgment relief under the preemption doctrine, arguing it should be treated like a generic drug manufacturer. *Id.* at *71. The court examined the factual record, noting that Eli Lilly participated in formulating the drug's label and marketing materials. *Id.* at *69, 76–77.[11] Based on these facts, the rationale supporting preemption of claims against generic drug makers was not applicable. *Id.* at *72. Eli Lilly had the ability to affect the drug's warnings and the duty to provide an adequate warning, therefore the claims were not preempted. *Id.* at *76–79.

Mitsubishi suggests the Court should instead follow the rationale of *In re Darvocet, Darvon & Propoxyphene Products Liability Litigation*, 756 F.3d 917 (6th Cir. 2014), which involved claims brought against a former brand name drug manufacturer that sold its NDA after a drug went generic. *Id.* at 923–24. The plaintiff filed suit eight years later, claiming the defendant continued to manufacture a generic form of the drug. *Id.* at 940. Because the defendant had completely divested itself of its rights over the drug, no longer had power over the drug's

[10] Plaintiff served discovery requests on Mitsubishi seeking information on a number of issues relevant to the Court's preemption analysis, including Mitsubishi's involvement in the regulatory approval of Invokana. As of today's date, this information has not been produced.

[11] This was particularly pertinent because "virtually every document used in marketing or distribution is considered 'labeling' under [FDA regulations]." *Id.* at *69 (quoting 21 C.F.R. § 202(i)(2)).

warnings, and was actually a generic drug manufacturer, the court found plaintiff's warning-based claims to be preempted. *Id.* Here, however, Invokana is not a generic drug and Mitsubishi has not sold its rights to it, rendering *In re Darvocet's* rationale inapplicable.

Mitsubishi's remaining authority, which involve claims against distributors of a drug, is equally distinguishable. *See In re Fosamax Prods. Liab. Litig.*, MDL No. 2243, 2012 U.S. Dist. LEXIS 5817, *27 (D.N.J. Jan. 17, 2012); *Stevens v. Cmty. Health Care, Inc.*, No. 117692, 2011 Mass. Super. LEXIS 263, *2 (Mass. Super. Ct. Oct. 5, 2011). Mitsubishi is no mere middleman distributor. Nor is it a powerless generic drug manufacturer. Mitsubishi designed and developed Invokana, provided support for Invokana's FDA approval, granted the marketing and distribution rights to its co-promoters, and generated significant revenue from the sale of the drug. As with the co-promoters in *In re Actos,* 2014 U.S. Dist. LEXIS 121648, there is no basis for preemption.

Discovery will show the precise powers or rights Mitsubishi retained over Invokana, its role in the labeling, design, promotion, and sale of Invokana, and the extent of its participation in the FDA approval process. These facts are highly relevant to the Court's analysis. *Id.* at *49–58 (analyzing co-promotion agreement, marketing activities, involvement in warning-related decisions, and communications with FDA as part of preemption analysis). As we remain at the Motion to Dismiss stage, the factual record is undeveloped and not before the Court. But the allegations that are before the Court establish that here, like in *Actos*, multiple pharmaceutical manufacturers entered into an agreement regarding the marketing and distribution of a brand name drug that caused significant harm. Like in *Actos*, there is no "sameness" requirement to prevent Mitsubishi (or any other Defendant) from ensuring Invokana is not inherently defective or that Invokana's labeling, marketing documents, and other materials adequately warn of the risks. And, like in *Actos*, Mitsubishi participated in the FDA approval of Invokana. Viewing all

factual allegations in the light most favorable to Plaintiff and drawing all reasonable inferences in his favor, there is no rational basis for preemption.[12]

2. Plaintiff's Design Defect Claims Are Not Preempted.

Mitsubishi's next argument mirrors that of its co-Defendants, seeking to expand the Supreme Court generic drug preemption decision, *Mutual Pharmaceutical Company v. Bartlett*, 133 S. Ct. 2466 (2013), to bar all pharmaceutical design defect claims. In essence, Defendants argue they should be able to develop, market, and sell a drug — even if it is known to be unreasonably dangerous — until the FDA affirmatively steps in to stop them, and even then they should bear no financial responsibility for the damage caused. Defendants posit that the FDA should serve as *de facto* judge and jury, leaving Courts without power and consumers without remedy. Such a premise should be rejected out of hand.[14]

The Supreme Court's preemption rulings evidence a distinct dichotomy in how the Court views claims against generic and brand name drug manufacturers. With respect to failure to warn claims, the Court held that claims against brand name drug manufacturers are not preempted by federal law, whereas most claims against generic manufacturers are impliedly preempted. *Wyeth v. Levine*, 555 U.S. 555, 573 (2009) (brand-name); *Mensing*, 564 U.S. at 618 (generic). Then in *Bartlett*, the Court found certain generic design defect claims were preempted. 133 S. Ct. at 2479. The Supreme Court has *never* found federal law to preempt claims against a brand name drug manufacturer. In fact, the deciding factor in both *Mensing* and *Bartlett* ultimately turned on a generic manufacturer's inability to change a drug's label. *Mensing*, 564 U.S. at 618; *Bartlett*, 133 S. Ct. at 2478–79. *See also Guenther v. Novartis Pharm. Corp.*, No. 08-456, 2013 U.S. Dist.

[12] In the alternative, Plaintiff requests the opportunity to take discovery to further develop these relevant facts. *See* Section D, *infra.*

[14] As Mitsubishi's arguments largely repeat those of its co-Defendants, Plaintiff refers the Court to his Opposition to Janssen and Johnson & Johnson's Motion to Dismiss, incorporating it by reference. *See Pl.'s Opp.*, Doc. 25 at 5–10. Plaintiff addresses Mitsubishi's additional arguments herein.

LEXIS 123696, *13–14 (M.D. Fla. Aug. 29, 2013) ("the FDCA's prohibition on label alterations by generic drug manufacturers was as central to the decision in [*Bartlett*] as it was in [*Mensing*]").[15]

As explained in Plaintiff's Opposition brief and the cases cited therein (Doc. 25 at 6–8), the preemption findings in *Mensing* and *Bartlett* turn on the duty of "sameness" imposed only on generic drug manufacturers, and therefore are not applicable to brand-name drugs. *Mensing*, 564 U.S. at 616–19; *Bartlett,* 133 S. Ct. at 2476–77. Mitsubishi attempts to discount this fact by referring to three non-binding cases citing *Mensing*, claiming this proves *Mensing* should be applied outside of the generic drug context. However, the first two cases simply cite *Mensing* for a generic legal premise, *Wos v. E.M.A.*, 133 S. Ct. 1391, 1398 (2013); *Horseman's Benevolent & Protective Assoc. v. Dewine*, 666 F.3d 997, 1000 (6th Cir. 2012), and the third examined the factually unique situation of a failure to warn claim in which the CBE process was unavailable to a brand name drug manufacturer. *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 41–43 (1st Cir. 2015). These cases are not persuasive, nor do they support expanding *Mensing* to preempt claims against brand-name drug manufacturers. In fact, the plain language of *Mensing* actually forecloses such a possibility:

> It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme.

[15] Mitsubishi concedes that design defect claims based on failure to warn are not subject to preemption. *Def.'s Mem.* at 15. As Plaintiff's failure to warn claims are sufficiently plead, Mitsubishi's preemption argument should be denied on this basis alone. *Sullivan v. Aventis*, No. 14-2939, 2015 U.S. Dist. LEXIS 107360, *21 (S.D.N.Y. Aug. 13, 2015) (denying preemption because "there is no federal law that prevents a manufacturer from complying with its state-law duty by strengthening a brand-name drug's warning label"). *See also Pl.'s Opp.*, Doc. 25 at 10.

Mensing, 564 U.S. at 626. *See also In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, MDL No. 2436, 2015 U.S. Dist. LEXIS 153972, *74 (E.D. Pa. Nov. 13, 2015) (relying on the above principle to hold "*Bartlett*—a case involving a generic manufacturer and following *PLIVA v. Mensing*—does not apply to the plaintiff's design defect claim against a brand-name manufacturer").

Mitsubishi's argument suggests this Court should ignore *Mensing's* clear limiting language. Instead, Mitsubishi would have the Court focus only on a single isolated clause from each of *Mensing* and *Bartlett*: "whether generic or brand-name," *Bartlett*, 133 S. Ct. at 2471; "without the Federal Government's special permission and assistance," *Mensing*, 564 U.S. at 623–24. Mitsubishi then urges the Court to combine these clauses, and in doing so, create an entirely new category of conflict preemption that would eliminate all brand-name design defect claims. *See Def.'s Mem.* at 13.

The recent medical device case, *Mullins v. Ethicon, Inc.*, No. 12-2952, 2015 U.S. Dist. LEXIS 101666 (S.D. Va. Aug. 4, 2015), rejected this argument, finding *Bartlett* declined to apply the impossibility preemption standard proposed by Defendants. *Id.* at *21–22.

> The defendants' focus demonstrates their misunderstanding of the nature of the impossibility found in *Mensing*, which was the direct conflict between the "state-law duty to change the label and the[ ] federal law duty to keep the label the same." In *Mensing*, there was no official regulatory process by which a generic could change its label, so the generic manufacturer was "barred" from taking the action state law required. This is completely different from the defendants' situation in the instant case. Unlike the law imposing the duty of sameness for generics, there is no federal law prohibiting design changes to medical devices, particularly changes representing advances in safety.

Id. at *23 (quoting *Mensing*, 564 U.S. at 618, 624).

Trahan v. Sandoz, Inc., No. 13-250, 2015 U.S. Dist. LEXIS 66869 (M.D. Fla. Mar. 26, 2015), also rejected Mitsubishi's argument, cautioning against reliance on *Bartlett's* "generic or brand name" clause in isolation. Instead, the clause must be examined in context, taking into

account existing Supreme Court precedent. *Id.* at *22–23, n.5. *Bartlett* explicitly recognized that "federal law establishes no safe-harbor for drug companies," 133 S. Ct. at 2479, and *Wyeth* found Congress did not intend for FDA oversight to preempt state tort law. 555 U.S. at 574–75. In fact, the Supreme Court recognized the vital importance of state tort suits to incentivize the prompt disclosure of drug safety risks and compensate injured parties. *Id.* at 579. In this context and on this basis, *Trahan* held:

> this Court does not interpret the *Bartlett* decision to change course and foreclose all design defect claims against prescription drug manufacturers in the absence of an express statement that it was doing so. To the contrary, because the *Bartlett* Court stated its express understanding that it was not providing a safe-harbor for drug companies, the Court declines to interpret *Bartlett* in such a way as to preempt [plaintiff's] claims ….

2015 U.S. Dist. LEXIS 66869, at *23, n.5. *See also*, *Hunt v. McNeil Consumer Healthcare*, 6 F. Supp. 3d 694, 704 (E.D. La. 2014) (addressing the "compelling policy justifications for reading *Bartlett* and *Mensing* narrowly so as to preserve the viability of products liability actions").

Mitsubishi's cited authority, *Batoh v. McNeil-PPC, Inc.*, No. 14-1462, 2016 U.S. Dist. LEXIS 31126 (D.D.C. Mar. 10, 2016) and *Barcal v. EMD Serono, Inc.*, No. 14-1709, 2016 U.S. Dist. LEXIS 35765 (N.D. Ala. Mar. 21, 2016), are wrongly decided. The Court should instead follow the more well-reasoned approaches of *Trahan, Mullins*, and the other cases cited in Plaintiff's previous briefing. *See Pl.'s Opp.*, Doc. 25 at 7–8. Regardless, neither *Batoh* nor *Barcal* —both of which were decided on summary judgment, not motions to dismiss — would support a finding of preemption here. *Batoh* and *Barcal* addressed preemption in the context of the redesign of a product *after* FDA approval, with *Batoh* specifically excluding pre-approval design defect claims from its analysis. *Batoh*, 2016 U.S. Dist. LEXIS 31126, *60; *Barcal*, 2016 U.S. Dist. LEXIS 35765, *10–11. The instant case, however, is largely based on the failure to design a reasonably safe drug *prior* to FDA approval. *See Pl. Opp.*, Doc. 25 at 7–9.

There is no arguable basis to find pre-approval design defect claims are preempted. Federal law did not prevent Mitsubishi from initially designing a reasonably safe drug prior to FDA approval. And, despite Mitsubishi's arguments to the contrary, *Bartlett's* so-called "stop selling" rationale does not apply. *Bartlett* held that "federal law establishes no safe-harbor for drug companies—but it does prevent them from taking certain ***remedial*** measures." 133 S. Ct. at 2479 (emphasis added). This recognizes that: (1) federal law does not eliminate a pharmaceutical company's duty of care, and (2) *Bartlett's* preemption findings were limited to remedial measures taken *after* FDA approval. As such, *Bartlett* has no application here.[17]

Federal law does not prohibit brand-name drug manufacturers from designing a reasonably safe drug before FDA approval, nor does it prohibit them from changing a drug's design post-approval to ensure it is reasonably safe. The "sameness" requirement that led to preemption in *Mensing* and *Bartlett* does not apply to brand name drug manufacturers. Therefore, claims against brand name drug manufacturers are not preempted. *See, e.g., In re Actos*, 2014 U.S. Dist. LEXIS 1749, at *36–37 ("It is well-settled that generic and brand name drugs are considered under different legal regimes, and the *Mensing* decision, therefore, has no application" to brand name drugs); *Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717, 721 (E.D. Pa. 2014) (*Bartlett* preemption does not extend to brand name drugs); *In re Tylenol*, 2015 U.S. Dist. LEXIS 153972, *73–74 (holding same); *Trahan*, 2015 U.S. Dist. LEXIS 66869, *21–22 (preemption does not affect duty to design reasonably safe product prior to FDA approval). *See also Ansagay v. Dow Agrosciences LLC*, No. 15-184, 2015 U.S. Dist. LEXIS 172470, *29 (D. Haw. Dec. 29, 2015)

[17] Mitsubishi also tries to avoid Plaintiff's pre-approval design defect claim by reference to *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 808 F.3d 281 (6th Cir. 2015). This argument was largely addressed in Plaintiff's prior briefing. *Pl.'s Opp.*, Doc. 25, at 9. Defendants ignore that the Sixth Circuit found "no physical impossibility between complying with a state law duty to exercise reasonable care in the process leading up to placing a drug on the market and complying with the federal government's process for approving drugs," and was "not persuaded that it is always impossible to comply with both state law duties and FDA regulations in the process leading up to FDA approval." *Yates*, 808 F.3d at 800 (quoting *Wimbush v. Wyeth*, 619 F.3d 632, 643 (6th Cir. 2010)).

("Unsurprisingly, courts construing *Bartlett* and *Mensing* have pointed out that preemption in both cases depended on the defendants' status as generic drug manufacturers"). Defendants had a duty to design a reasonably safe drug, and federal law did not prevent them from doing so. As such, Plaintiff's claims are not preempted.

3. Mitsubishi's Preemption Arguments Are Premature.

In addition, Defendants' preemption arguments are fact-based and inappropriate at the Motion to Dismiss stage. *See Fields v. Alcon Labs., Inc.*, No. 13-197, 2014 U.S. Dist. LEXIS 34897, *9 (S.D. Ill. Mar. 18, 2014) (Herndon, J.); *Eike v. Allergan, Inc.*, No. 12-1141, 2014 U.S. Dist. LEXIS 34894, *17 (S.D. Ill. Mar. 18, 2014) (Herndon, J.). Mitsubishi's NDA-based preemption argument implicates the terms of the Defendants' licensing agreement, the rights and responsibilities Mitsubishi retained over Invokana, the extent of Mitsubishi's participation in the approval and labeling of Invokana, and its involvement in the marketing and promotion of the drug. None of these facts are before the Court. Defendants' design defect preemption claim also implicates important factual questions. The argument's foundation, faulty as it may be, rests on the presumption that Plaintiff's claim implicates a "major change" under FDA regulations, triggering the need for FDA approval. *See* 21 C.F.R. § 31.70(b)(2)(i). This, of course, has not been determined. As such, Mitsubishi's preemption arguments are premature, rest on a faulty interpretation of the law, and are wholly without merit.

C. The Complaint Pleads Plausible Claims For Relief Sufficient To Satisfy Rule 8 and, Where Applicable, Rule 9.

When ruling on a 12(b)(6) motion to dismiss, the court looks to the complaint to determine whether it satisfies the threshold pleading requirements of Federal Rule of Civil Procedure 8. *In re: Yasmin and Yaz (Drospirenone) Mktg. Sales Pracs. & Prods. Liab. Litig.*, 692 F. Supp. 2d 1012, 1017 (S.D. Ill. 2010) (Herndon, J.). The court must accept all

facts in the complaint as true, view them in the light most favorable to Plaintiff, and draw all reasonable inferences in his favor. *Bonte v. U.S. Bank, N.A.*, 624 F.3d 461, 463 (7th Cir. 2010). "The bar to survive a motion to dismiss is not high." *Id.* A complaint survives dismissal so long as it "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

Rule 8(a)(2) requires that a complaint provide "a short and plain statement of the claim showing the pleader is entitled to relief" and "give the defendant fair notice of what the claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. The plaintiff need not plead particularized facts, but the factual allegations in the complaint must be enough to raise a right to relief above the speculative level. *Twombly*, 550 U.S. at 555. A claim is plausible on its face when the plaintiff pleads factual content allowing the court to draw a reasonable inference that the defendant is liable for the alleged misconduct. *Iqbal,* 556 U.S. at 678. In keeping with these directives, pleading requirements are meant to "focus litigation on the merits of a claim rather than on technicalities that might keep plaintiffs out of court." *Bausch v. Stryker Corp.*, 630 F.3d 546, 559 (7th Cir. 2010) (citations and quotations omitted).

Mitsubishi makes few new arguments, and instead references the arguments made by its co-Defendants. In response, Plaintiff refers the Court to his Opposition to those arguments, and incorporates them by reference. *See Pl.'s Opp.*, Doc. 25 at 10–18. Mitsubishi's additional arguments, which focus solely on the case *Guidry v. Janssen Pharmaceuticals, Inc.*, No. 15-4591, 2016 U.S. Dist. LEXIS 18966 (E.D. La. Feb. 17, 2016), are unpersuasive.

Guidry — an unpublished, out-of-Circuit, district court decision examining a different complaint, filed by a different party, who was represented by different counsel, in which the only

apparent similarity is that both Mr. Schurman and Ms. Guidry allege injury caused by the same defective drug — has no bearing here. Given the pleading-specific nature of a Rule 12(b)(6) inquiry, *Guidry* does not affect the Court's analysis. Instead, as set forth in Plaintiff's previously filed opposition brief and the cases cited therein, Plaintiff states a cause of action as to each count alleged. *See Pl.'s Opp.*, Doc. 25 at 12–18.

1. Design Defect

Plaintiff's factual allegations sufficiently describe Invokana's design defects and state a plausible claim for relief. As alleged, Invokana is designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. *Compl.* at ¶ 24. As a result, excess glucose is not metabolized, but instead is excreted through the kidneys. *Id.* This process places the kidneys under duress and increases the risk of severe kidney damage. *Id.* at ¶¶ 24, 26–27. Diabetics already are at heightened risk for kidney disease, making Invokana's method of action especially problematic. *Id.* at ¶ 24. This defective design was a substantial and contributing factor in causing Plaintiff's kidney injury. *Id.* at ¶ 63.

These factual allegations are sufficient to "give the defendant fair notice of what the claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. Accordingly, Plaintiff's Complaint adequately states a claim. *See Smith v. Boehringer Ingelheim Pharm., Inc.*, 886 F. Supp. 2d 911, 926 (S.D. Ill. 2012) (Herndon, J.).

2. Failure to Warn

Plaintiff also stated a plausible claim for failure to warn. Like its co-Defendants, Mitsubishi glosses over the fact that it must ***adequately*** warn of the risks associated with its products, providing sufficient information to inform physicians and users of the severity and magnitude of the risk. *See, e.g.*, *D.W.K. v. Abbott Labs., Inc. (In re Depakote)*, No. 14-847, 2015 U.S. Dist.

LEXIS 108399, *14–15 (S.D. Ill. Feb. 14, 2015) (Rosenstengel, J.).[18] Despite Mitsubishi's statements to the contrary, the Complaint has numerous allegations explaining how Invokana's warnings were inadequate and how this inadequacy caused Plaintiff's injury. For example:

- "Defendants knew of the significant risk of kidney damage caused by ingestion of INVOKANA. However, Defendants did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community of the severity such risks. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote the sale of INVOKANA and willfully deceived Plaintiff, his health care professionals, the medical community, and the general public as to the health risks and consequences of the use of the INVOKANA. As a direct result, in or about February 2015, Plaintiff was prescribed and began taking INVOKANA, primarily to treat diabetes." *Compl.* at ¶¶ 30–32.

- "Portions of the prescribing information relied upon by Plaintiff and his health care professionals, including the 'Warnings and Precautions' section, purport to expressly include the risks associated with the use of INVOKANA, but those risks are neither accurately nor adequately set forth." *Id.* at ¶ 124.

- "The concealment of information and the misrepresentations about INVOKANA were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them so that Plaintiff would request and purchase INVOKANA and his health care providers would prescribe and recommend INVOKANA. Plaintiff, his doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk posed by INVOKANA. Had Defendants not concealed or suppressed information regarding the severity of the risks of INVOKANA, Plaintiff and his physicians would not have prescribed or ingested the drug." *Id.* at ¶¶ 193–95.

As alleged, Defendants knew Invokana posed a high likelihood of causing severe kidney injury and they knew Invokana users were several times more likely to report suffering this injury. *Id.* at ¶¶ 26–28. Despite this, Defendants failed to adequately inform Plaintiff or his physicians of this risk. *Id.* at ¶¶ 79–83. Invokana's product labeling and accompanying materials failed to accurately or adequately communicate the comparative severity, duration, and extent of the risk of kidney injury posed by Invokana, or otherwise provide sufficient information on the symptoms or scope of Invokana's effect on kidney function. *Id.* at ¶ 82. Instead, Defendants

[18] Mitsubishi challenges Plaintiff's reliance on *D.W.K.*, claiming Plaintiff's Complaint should contain the same level of detailed facts presented before the *D.W.K.* court. However, Mitsubishi fails to mention that *D.W.K.* was decided on summary judgment, based on the facts and evidence developed during discovery. 2015 U.S. Dist. LEXIS 108399, *4.

aggressively promoted the drug, downplaying and suppressing these dangers in Invokana's labeling, as well as in marketing and promotional campaigns. *Id.* at ¶¶ 31, 82. Plaintiff and his physicians relied on these representations and omissions when choosing to prescribe and ingest Invokana. *Id.* at ¶¶ 81–82, 90. Had the true risk of kidney injury been adequately disclosed, Plaintiff's physician would not have prescribed Invokana and Plaintiff would not have ingested Invokana. *Id.* at ¶¶ 42, 195. These factual allegations state a plausible claim for relief. *See In re Depakote*, 2015 U.S. Dist. LEXIS 108399, *12.

3. Express Warranty

As set forth in response to the Johnson & Johnson Defendants' Motion to Dismiss, Plaintiff's Complaint contains numerous allegations supporting his claim for breach of express warranty. *Pl.'s Opp.*, Doc. 25 at 16. In accordance with the arguments set forth therein, Mitsubishi's motion to dismiss should be denied.

D. Request for Discovery.

To the extent the Court chooses to entertain Mitsubishi's jurisdiction or preemption arguments, Plaintiff respectfully requests leave to conduct discovery. *See Pl.'s Opp.*, Doc. 25 at 18–19. Mitsubishi posits that its status as a foreign corporation particularly insulates it from jurisdictional discovery, citing *Central States, Southeast & Southwest Areas Pension Fund v. Reimer Express World Corp.*, 230 F.3d 934 (7th Cir. 2000), for support. Despite Mitsubishi's broad statements, *Central States* does not stand for the proposition that jurisdictional discovery should not be permitted. In fact, *Central States* recognized the propriety of allowing targeted discovery against a foreign defendant when personal jurisdiction is in question. *Id.* at 947.

"[A] plaintiff is entitled to jurisdictional discovery if he or she can show that the factual record is at least ambiguous or unclear on the jurisdiction issue." *Andersen v. Sportmart, Inc.*, 179 F.R.D. 236, 241 (N.D. Ind. 1998) (granting jurisdictional discovery with respect to foreign

national). As set forth above, Plaintiff sufficiently established personal jurisdiction over Mitsubishi. Should the Court disagree, Plaintiff's allegations coupled with Invokana's astronomical sales figures make a colorable showing that is more than sufficient to justify jurisdictional discovery.[19]

If permitted to conduct discovery for jurisdictional and preemption purposes, Plaintiff would seek, at a minimum, Corporate Representative depositions pursuant to Federal Rule of Civil Procedure 30(b)(6) and related document requests on the following: (1) Mitsubishi's corporate structure; (2) its involvement in the development, manufacture, approval, labeling, sale, marketing, and promotion of Invokana; (3) the sale, distribution, and marketing of Invokana in Illinois; (4) contractual agreements among the Defendants; (5) studies and other clinical trials related to Invokana; (6) the design, development, and testing of Invokana; and (7) scientific studies showing increased risks of Invokana and related communications with the FDA.

E. Alternately, Plaintiff Requests the Opportunity to Amend His Complaint.

Alternately, should this Court find Plaintiff's Complaint defective in any way, Plaintiff respectfully requests leave to amend. Under Rule 15(a)(2), leave to amend should be "freely" granted when "justice so requires." Although Plaintiff firmly believes his Complaint is sufficient as is, if this Court determines otherwise, Plaintiff should be afforded the opportunity to reallege his claims in a manner acceptable to all parties and this Court.

CONCLUSION

For the foregoing reasons, this Court should deny Mitsubishi's motion to dismiss.

[19] Mitsubishi also asks the Court to shift the costs of jurisdictional discovery to Plaintiff. Strangely, Mitsubishi's sole support for this request is a decision from the District of South Carolina denying a request for cost shifting due to the failure to submit sufficiently detailed supporting evidence. *Ashmore v. Allied Energy*, No. 14-227, 2016 U.S. Dist. LEXIS 8012, *7–8 (D.S.C. Jan. 22, 2016). Here, Mitsubishi took it one step further by submitting no evidence in support. In accordance with Mitsubishi's own authority, the Court should deny its cost-shifting request.

Dated: May 2, 2016

Respectfully submitted,

/s/ Roger C. Denton

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 2nd day of May, 2016, a copy of the foregoing was filed electronically with the Clerk of Court to be served via the Court's electronic case filing system on all counsel of record.

/s/ Roger C. Denton